

AUG - 8 1996

K955916
510 (k) Summary

CLASS III

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Device Information:

proprietary name: Townley Total Elbow System
common name: Prosthetic, Total Elbow
classification name: Prosthetic, Total Elbow

Predicate Device: Capitello- Condylar Total Elbow manufactured by Johnson & Johnson

Device Description:

Humeral Component: The humeral component of the Townley Total Elbow is manufactured of Cobalt Chrome (ASTM F-799). It is offered in both right and left designs and features a stabilizing intramedullary stem that is angled in five degrees of valgus to accommodate the normal carrying angle of the elbow. The proximal, bone-interfacing, non-articulating side of the body is designed with a squared receptical to accept the similarly remodeled humeral condyles. The articulating surface of the humeral component is contoured to allow a snap-fit with the ulnar component and is extended laterally to articulate with the radial head. It is offered in three sizes: 35mm, 40mm, and 45mm.

Ulnar Insert: The ulnar insert is manufactured of UHMWPE. The insert is designed to snap onto the humeral component and provide a stable joint while retaining multiplanar flexibility. It is offered in two sizes: small and large.

Ulnar Tray: The ulnar tray is manufactured of Cobalt Chrome (ASTM F-799). It features a L-shaped body which provides support for the polyethylene insert as well as a stem that aids in fixation. It is offered in two sizes: small and large.

Intended Use:

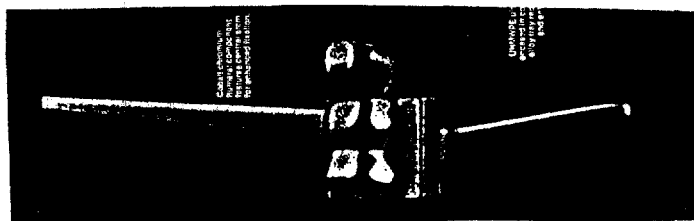
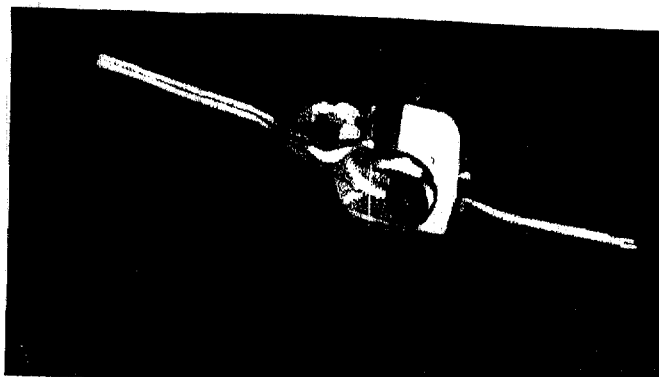
The Townley Elbow System contains three components which are intended for single use. Cement fixation of the components is required.

Indications: Osteoarthritis, Rheumatoid arthritis with severe elbow pain and limited joint motion.

Contraindications: Excessive bone loss, Septic arthritis, Periarticular osteomyelitis, and General health problems.

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Comparison of the Townley Elbow System vs. the Capitello-Condylar System



Photograph of the Townley Elbow

Photograph of the Capitello-Condylar Elbow

Humeral Component	Cobalt Chrome	Sizes Available
Capitello-Condylar	Yes	2
Townley System	Yes	3

Ulnar Tray	Cobalt	Universal Tray (can be used on right or left)	Sizes Available
Capitello-Condylar	Yes	No	4
Townley System	Yes	Yes	2

Ulnar Tray Insert	Snapfits onto Humeral Components	UHMWPE	Universal Insert (can be used on right or left)
Capitello-Condyl.	No	Yes	No
Townley System	Yes	Yes	Yes

Total Elbow Joint	Normal Flexion/Extension	Resists Dislocation	Non-constrained in Varus/Valgus
Capitello-Condyl.	Yes	No	No
Townley System	Yes	Yes	Yes

The Townley Total Elbow Replacement ensemble is substantially equivalent to the Capitello-Condylar prosthesis manufactured by Johnson & Johnson Orthopaedics. The two systems are identical relative to general purpose and concept of elbow replacement as well as the materials used. The only dissimilarity relates to certain details in implant designing that include: 1) allowance for a limited degree of varus/valgus excursion, 2) a modular polyethylene insert, 3) a snap-fitted prosthetic articulation, and 4) the right/left universability of the ulnar component. The two systems are equally proficient in allowing normal flexion and extension motion.